

10



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,600	08/20/2003	Hans-Jurgen Gutke	60636(50551)	5568
21874	7590	07/12/2004	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			MCINTOSH III, TRAVISS C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/644,600

Applicant(s)

GUTKE ET AL.

Examiner

Traviss C McIntosh

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10 and 13, drawn to compounds having macrolides as the transportophores, or the compounds represented by the structures in claims 9 or 10, classified in class 536, subclass 7.1.
 - II. Claims 1, 11, and 13, drawn to compounds represented by the structure in claim 11, classified in various classes and subclasses depending on the variables.
 - III. Claims 1, 12, and 13, drawn to compounds represented by the structure in claim 12, classified in various classes and subclasses depending on the variables.
 - IV. Claims 1 and 13-15, drawn to compounds of claim 1 wherein C is an anti-inflammatory agent, classified in various classes and subclasses depending on the actual structure of the compound.
 - V. Claims 1, 13, and 16-17, drawn to compounds of claim 1 wherein C is an anti-infectious agent, classified in various classes and subclasses depending on the actual structure of the compound.
 - VI. Claims 1, 13, and 18, drawn to compounds of claim 1 wherein C is an anti-cancer agent, classified in various classes and subclasses depending on the actual structure of the compound.

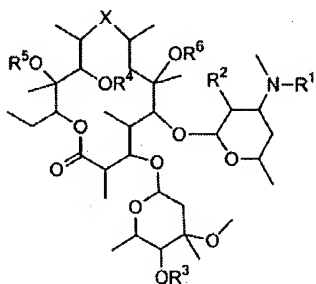
- VII. Claims 1, 13, and 19, drawn to compounds of claim 1 wherein C is a fluorescent molecule, classified in various classes and subclasses depending on the actual structure of the compound.
- VIII. Claims 1, 13, and 20-21, drawn to compounds of claim 1 wherein C is an immune-suppressant agent, classified in various classes and subclasses depending on the actual structure of the compound.
- IX. Claims 1, 13, and 22, drawn to compounds of claim 1 wherein C is an agent for treating a hematopoietic disorder, classified in various classes and subclasses depending on the actual structure of the compound.
- X. Claims 1, 13, and 23-24, drawn to compounds of claim 1 wherein C is an agent for treating a metabolic disease, classified in various classes and subclasses depending on the actual structure of the compound.
- XI. Claim 25, drawn to a composition comprising the compound of formula I, classified in class 514, various subclasses depending on the actual structure of the compound.
- XII. Claim 26, drawn to a method of treating an inflammatory disorder using the compound of claim 1 wherein C is an anti-inflammatory agent, classified in class 514, various subclasses depending on the actual structure of the compound used.
- XIII. Claim 27, drawn to a method of treating an infectious disease using the compound of claim 1 wherein C is an anti-infectious agent, classified in class 514, various subclasses depending on the actual structure of the compound used.

Art Unit: 1623

- XIV. Claim 28, drawn to a method of treating a cancer using the compound of claim 1 wherein C is an anti-cancer agent, classified in class 514, various subclasses depending on the actual structure of the compound used.
- XV. Claim 29, drawn to a method of treating an allergy using the compound of claim 1 wherein C is an allergy-suppressive agent, classified in class 514, various subclasses depending on the actual structure of the compound used.
- XVI. Claim 30, drawn to a method of treating an immune disorder using the compound of claim 1 wherein C is an immune-suppressing agent, classified in class 514, various subclasses depending on the actual structure of the compound used.

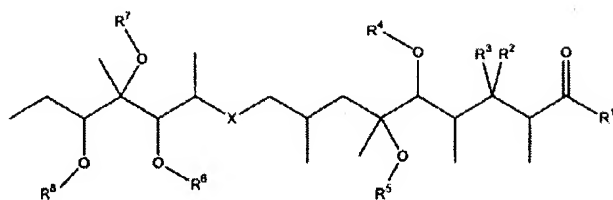
The inventions are distinct, each from the other because of the following reasons:

Groups I-III are independent and distinct from each other as they are drawn to compounds which have divergent moieties in the T position. The compound of group I requires a macrolide substructure as set forth by the following:



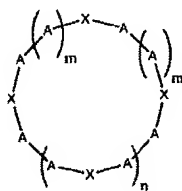
, wherein the compound of group II requires a linear substructure as set forth by the following:

Art Unit: 1623



, wherein the compound of group

III requires a cyclic substructure as set forth by the following:



. Each of groups I-III are directed to compounds which are

recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects, and reactive conditions. It is noted that a reference disclosing a compound of one group would not necessarily disclose a compound of the other two groups. Additionally, the level of skill in the art is not such that one invention would be obvious over the other, i.e., they are patentable over each other.

Chemical structures which are similar are presumed to function similarly, while chemical structures which are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of *Application of Papesch*, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), and *In re Lulu*, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure. As set forth supra, the

Art Unit: 1623

structures of groups I-III are not structurally similar and thus, a search for one group would not be required for the other groups and a reference rendering one group obvious would not necessarily render the other groups obvious.

Groups IV-X are independent and distinct from each other as they are drawn to compounds which have divergent moieties in the C position. Groups IV-X are drawn to various compounds which have various groups attached in the C position which are defined by their function. As set forth supra, in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure. It is noted that the agents in the C position of groups IV-X indeed have different functions. A reference disclosing or rendering obvious a compound of one group would not necessarily disclose or make obvious a compound of the other groups.

Moreover, each of groups I-III are independent and distinct from each of groups IV-X as a search for each of groups I-III requires the substructures as set forth supra, while a search for groups IV-X would not require said substructure search. Additionally, a search for groups VI-X requires a search of the specific functional moiety of the C group, while a search for groups I-III would not require said functional search. Moreover, a reference rendering one of the groups obvious would not necessarily render the other obvious and a search for one of the groups is not required for the others. As such, a search of the independent and distinct inventions of groups I-X would indeed impose an undue burden upon the examiner in charge of the instant application.

Art Unit: 1623

Inventions I-X and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the claimed products can be practiced with another patentably distinct product, such as with the compounds as set forth by Smith, III et al. (US Patent 6,455,570 – see claim 7).

Inventions I-X and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the claimed products can be practiced with another patentably distinct product, such as with the compounds as set forth by Kobayashi et al. (US Patent 6,242,437 – see abstract).

Inventions I-X and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the claimed products can be practiced with another patentably distinct product, such as with the compounds as set forth by Littlefield et al. (US Patent 6,653,341 – see claim 1 for example).

Inventions I-X and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the claimed products can be practiced with another patentably distinct product, such as with the compounds as set forth by Satoh et al. (US Patent 5,910,499 – see claim 15).

Inventions I-X and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the claimed products can be practiced with another patentably distinct product, such as with the compounds as set forth by Linhardt et al. (US Patent 4,847,338 – see claim 8).

It is noted that if applicant elects a compound from groups I-X, the composition correlative to said elected group will be examined together with the compound. That is, if applicant elects the compound of Group I, for example, they are entitled to the search of the composition of Group XI comprising the same.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, restriction for examination purposes as

Art Unit: 1623

indicated is proper. It would indeed impose an undue burden upon the examiner in charge of this application if the instant restriction requirement is not set forth.

Claims 1-26 are generic to a plurality of disclosed patentably distinct species comprising a plethora of divergent compounds represented by the compound of claim 1. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. By a single species it is meant a single compound. The compound may be named in any of four ways: 1) according to IUPAC standard, 2) by a pictorial representation of the compound, 3) by setting forth the specific chemical group that each variable of the Markush group represents, or 4) by naming a claim or an example which itself sets forth a single compound.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a complete reply to this requirement must include an identification of the species that is elected and a listing of all claims readable thereon.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

Art Unit: 1623

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

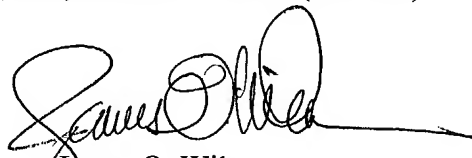
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
June 28, 2004



James O. Wilson
Supervisory Patent Examiner
Art Unit 1623